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Summary: Quality Institute Conference
Making the Laboratory a Partner in Patient Safety
Atlanta, Georgia, April 13-15, 2003

The Quality Institute conference, "Making the Laboratory a Key Partner in Patient Safety" was convened by Centers for Disease Control and Prevention and 40 partners and sponsoring organizations in Atlanta on April 13-15, 2003. The meeting program and presentations are available on the CDC website (http://www.phppo.cdc.gov/mlp/qiconference).

Keynote Presentations

The keynote speakers were **Lucian Leape M.D**., from Harvard School of Public Health and a member of the Committee on Quality of Health Care In America of the Institute of Medicine, and **Brent James, M.D**. from Intermountain Health Care and the Institute of Health Care Delivery Research.

Lucian Leape, MD's presentation was entitled "Patient Safety: The New Accountability." Dr. Leape emphasized that the idea that medical errors are caused by bad systems is a transforming concept. The accident causation model is a useful framework for medical errors. The accident causation model consists of latent errors, system defects, triggering factors and unsafe acts, which in the absence or breakdown of defenses, result in errors. When there are inadequate defenses, errors result in accidents. The take home message from Dr. Leape's presentation were: (1) that medical injuries are not inevitable; and that most medical injuries are preventable; and (2) that medical injuries are not the fault of individuals but are the result of faulty systems; (3) medical injuries are everyone's responsibility; and (4) It's much easier to change systems than to change people. Finally Dr. Leape emphasized that improvement in patient safety requires accountability and responsibility. This would require a culture change in which everyone must have a clear responsibility to make the changes needed, that responsibility for safety must trump personal preferences, and that safety is everyone's responsibility. Meaningful accountability, said Dr. Leape, is collaborative supportive and reciprocal activity involving professionals, hospitals and regulators.

Brent James, MD, presentation was entitled "Quality as a Core Business Strategy." by describing 19th-century advances in health-care and clinical education, requirements for licensing, advances in science, and the internal organization of hospitals. Dr. James emphasized the importance of organizing effort is to improve quality around the core business of clinical medicine. Improvements at Intermountain Health consist of efforts to improve clinical programs clinical support services, patients' perceptions of quality, administrative support services, and integration of clinical support services and clinical services. Dr. James emphasized that experience of Intermountain Health Care could be summarized in three main ideas. First, there is compelling evidence that health outcomes could be much better; second, experience shows it is possible to close the quality gap, and third, a business case can be made for quality improvement because better patient results can produce significant cost savings.

Perspectives Panel

Lee H. Hilbourne, M.D., MPH. Director of the UCLA Center for Patient Safety and Quality, Panel coordinator

Nancy Green, M.D. from the March of Dimes gave a presentation, "The Patient and Family Experience" described a case of kernicterus as result of an ABO incompatibility, which resulted in tragic injury to child as a consequence of multiple errors throughout the health-care system. The child's blood type was not drawn, a bilirubin test was not performed, provider's responses to parental concerns were overly optimistic, physician and nurse responsibilities were not adequately enforced, primary staff responsibilities were unclear, and there was inadequate use of the laboratory. The presentation was an excellent example of the accident causation model in medicine.

Matthew B. Weinger, M.D., Director of the San Diego Center for Patient Safety, spoke on the topic "Laboratory Medicine's role in Patient Safety at the 'Sharp' End: One Clinician's Perspective." Dr. Weinger described the operating room as a clinical microsystem. Dr. Weinger emphasized the hidden costs of medical technology. Dr. Weinger emphasized the importance of integrating laboratory systems with clinical information systems. This tighter integration, however, may produce new modes of system failure. These new modes of system failure consist of usability issues in which clinician's misses or misreads laboratory results, automation with its resulting reliance on electronic clinical reminders leading to assumptions that all is okay if no reminders are given, tighter coupling in which a single error can be propagated to many patients very quickly, workflow issues in which difficulty accessing a system precludes the use of the system when really needed, and technology failure which a system crashes and results are not available or ability ordering is unavailable.

Nancy Foster, PhD, Senior Associate Director for Policy of the American Hospital Association spoke on "Hospital Perspectives on Safety." Hospitals' perspectives on patient safety and quality is that more support and less "encouragement" is needed in patient safety and quality, that hospitals need to reduce redundancy in monitoring and reporting on patient safety and quality, and that hospitals need information not just data. Dr. Foster said that important issues to consider in assessing potential changes to improve patient safety including the importance of controlled observations in interventions, the use of surrogate endpoints (errors) vs. clinical outcomes (adverse events), the generalizability of practice benefits outside of research settings, and the possible harm that may come from any intervention even one from a "safety practice." Laboratory safety is a piece of the larger problem. Overall improvement is needed for the whole (health-care system).

Linda McKibben, PhD from the Centers for Disease Control and Prevention, spoke on the "Government's Role in Crossing the Quality Chasm." The federal government has a role in protecting and promoting the public well-being. The Quality Chasm cuts across boundaries, and the size and scale of the Quality Chasm warrant a broad, coordinated long-term approach. The laboratory is a natural focus for efforts to improve quality for several reasons: the large number of laboratory tests that are performed each year, laboratory expertise in quality systems approach; experience with standardization, automation, and computerization; a culture of

teamwork, measurement, and reporting; experience with statutory and regulatory approach to quality assurance; the presence of diverse vigorous organizations engaged in quality assurance activities; and nongovernmental organizations active in developing and implementing guidelines and standards. The tools needed are performance measures, national reporting or monitoring, and a proposed Quality Institute. Issues that need to be addressed are whether an approach should be statutory and regulatory; the role of guidelines and standards; the role of research, education, and training; and the role of cooperative agreements and partnerships.

Mark Hiepler, JD, from Hiepler and Hiepler, addressed important legal issue in laboratory tests. Legal actions against laboratories or physicians have been based on medical malpractice. A new basis of legal action against the laboratory or the physician is a breach of fiduciary duty. A breach of fiduciary duty can occur in the presence of capitation because of potential incentives not to treat, potential impact of delayed treatment, or potential financial conflicts of interest that are unknown to patients.

Experiences Panel

Ana Stankovic, MD, PhD, Division of Laboratory Systems, CDC, panel leader

Robert L. Phillips, Jr. M.D., MSPH, from the American Academy of Family Physicians, spoke on "Laboratory Safety and Quality Primary Care: Evidence and Evolution." Dr. Phillips reported that most health care is provided in the primary care setting. Laboratory errors in primary care occur in 3.4 per thousand visits. Most of the errors in ambulatory care occur in the pre-analytic and the post-analytic phases of testing. An international study of errors in primary care found that errors in implementing laboratory investigations and responding to abnormal laboratory tests were among the five most common categories of errors.

Kenneth Freeman, MBA, chief executive officer of Quest Diagnostics Inc. spoke on the topic "Six Sigma Approach to Laboratory Quality: the Quest Diagnostics Inc. Experience." Quest a for-profit reference laboratory service, has adopted the Six Sigma approach. The goal is to achieve virtual "perfection" in reducing defects per million opportunities. The company uses a rigorous methodology, and the approach is customer focused and data driven. Mr. Freeman said that approach requires a change in corporate culture with a senior leadership role, the commitment of talented and dedicated personnel, a willingness to change the status quo, and goals to improve patient benefits. Cost reduction becomes an outcome of the approach, rather than the goal of the approach.

Richard J. Zarbo, M.D., D.M.D., from the College of American Pathologists (CAP) gave a presentation entitled, "CAP Q-Probes and Q-Tracks: 15 years of Laboratory Indicator Development." The CAP has sponsored two programs over 15 years that have produced many publications and that have received several awards. The topics addressed include clinicians/customer performance, laboratory/pathologist performance, and patient perceptions of care. The programs deliverables included definitions of the drivers of quality care, standardized data collection tools, external benchmarks, peer group comparisons, best practices in performance profiles. The main message from the CAP experience is that there are opportunities

for improvement in existing services. Improvements in patient safety related policies can be made in the pre-analytic phase of testing and enhanced communication is possible in the post-analytic phase testing.

Michael Laposata M.D., Ph.D., from the Massachusetts General Hospital, spoke on "Reducing Medical Errors by Providing Expert Advice in the Selection and Interpretation of Laboratory Tests." Dr. Laposata indicated that the highest incidence of errors in the total testing process occurs in the selection of tests and the interpretation of test results. Dr. Laposata described three strategies to reduce errors. First, his laboratory uses reflex testing as much as possible. Second, his laboratory provides patient specific narratives for complex laboratory evaluations as is done in anatomic pathology and radiology. Third he proposes the creation of a national group of experts in areas of laboratory medicine to provide narrative interpretations and link experts to physicians requesting advice and their pathologists through Web based Internet services.

Workgroups

National Report Workgroup

The meeting attendees thought a *National Report on the Quality of Laboratory Services* would be useful to laboratory medicine professionals, clinicians and other providers, accrediting agencies, licensing boards, standard-setting organizations, and federal government agencies. There were mixed opinions regarding the usefulness of a national report for the public, insurers or other payers, policymakers, and health care administrators.

The meeting attendees stated that the framework must incorporate the total testing cycle. The framework that is being used for the *National Report on the Quality of Health Care in United States* could be used as a framework for a *National Report on the Quality of Laboratory Services*.

An initial set of topics discussed for the contents of a *National Report on the Quality Laboratory Services* should include sources of error in the testing cycle, test appropriateness and effectiveness, information transfer to improve test ordering and test interpretation, the role of incentives for reporting information on the quality of laboratory services, the workforce and resources needed, and a synopsis of patient safety projects. Topics such as genetic testing, home testing, point-of-care testing, and direct to consumer marketing of laboratory tests were judged to be less useful. Meeting attendees agreed that laboratory medicine professionals have expertise in test ordering and test interpretation as well as quality assurance and quality control that could improve patient safety throughout the health-care system

Indicators of the Quality of Laboratory Services Workgroup

The goal of establishing indicators would be to assure the appropriate use of laboratory tests. A Quality Institute may be needed. Laboratory tests could be used as indicators of quality for certain medical conditions. Issues identified were the feasibility of monitoring, the financial or

logistical constraints in collecting data, and the need for guidelines for the best practices. (Check this!)

Meeting attendees addressed the issue of whether mandatory or voluntary participation in data collection for the quality of laboratory services would lead to valid indicators. This is an important issue and there was mixed response. Voluntary participation would be problematic because laboratories might not participate leading to bias. Incentives for participation might encourage voluntary participation and reduce bias. There was more agreement that mandatory participation would lead to valid data but if punitive, some laboratories would "game" the system. There is also concern about establishing another unfunded mandate.

The meeting attendees thought the scope of indicators should be both national and state level. The indicators were judged to have different importance for different stakeholders, but indicators were thought to be generally important to most stakeholders; indicators would be most useful to laboratories and health-care organizations followed by payers and government. The timeliness of laboratory test should be a quality indicator but it would be necessary to specify the patient setting, the conditions, and laboratory tests. Trended data are essential and there was agreement on the need for baseline data.

Interdisciplinary involvement would be essential in developing indicators. There was some variation in attendees regarding access to the original data (data without identifiers). A Quality Institute, laboratory professionals and researchers should have access to the original data. There was less agreement on whether providers, payers, and government should have access to the original data. Meeting attendees generally thought it important to report results at a national level and there was somewhat less agreement about the importance of reporting data at a state level, by health-care organization, type of laboratory, individual laboratory, type of laboratory test, individual laboratory test, and payers.

Workgroup on Establishing a Quality Institute

Most participants thought there was need for a new ongoing Quality Institute to address patient safety and quality issues. A Quality Institute should not duplicate the activities of existing professional organizations. Attendees thought that the proposed work of a Quality Institute in addressing patient safety is generally not being done by existing organizations.

The ideal characteristics of the Quality Institute would be an independent organization, capable of rapid decisions, led by an independent board of directors. The Quality Institute could be spun off from existing organizations. A Quality Institute could bridge traditional boundaries in medicine. The Quality Institute should have broad representation and should avoid association with a particular segment of the industry.

The Quality Institute should be an independent not-for-profit organization with representation from consumers and policymakers. The board of the Quality Institute should include broad representation from laboratories, users, consumers, payers, insurers and other groups.

A Quality Institute should have a broad mission that includes surveillance, research, education, clearing house for patient safety practices, policy analysis, and identification of best practices for patient safety and quality laboratory services.

A Quality Institute should be supported by a mixture of public and private funding. The Quality Institute could partner with other laboratory professional organizations, other patient safety organizations, and other health-care improvement organizations.

Closing Summary

Robert Martin, PhD, Director of the Division of Laboratory Systems, closed the meeting with an overview of the meeting. The main message of the meeting was that the laboratory has a major role in patient safety. Quality issues, particularly around pre-analytic and post-analytic phases of testing are of critical importance. There is a need for a national report on patient safety, and indicators of quality of laboratory services. Many individuals and organizations are providing leadership -- including professional organizations, government, and payers -- but there is a need for a focal point, such as Quality Institute for efforts to improve patient safety and the quality of laboratory services. The Division of Laboratory Systems would continue the process by providing a summary of the meeting on the CDC website, providing feedback to the leadership of CDC. Dr Martin invited the meeting steering committee to participate in conference calls to plan further work on indicators and national report.